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Accuracy of Self-reported HIV Status Among African Men and Transgender Women Who Have Sex with Men Who were Screened for Participation in a Research Study: HPTN 075

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Abstract

Some HIV-infected individuals in research studies may choose not to disclose knowledge of their HIV status to study staff. We evaluated the accuracy of self-reported HIV status among African men and transgender women who have sex with men and who were screened for a research study. Sixty-seven of 183 HIV-infected participants reported a prior HIV diagnosis. Samples from the remaining 116 participants were tested for antiretroviral (ARV) drugs. Thirty-six of the 116 participants had ARV drugs detected, indicating that they were on antiretroviral treatment; these

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Compliance with Ethical Standards

Conflicts of Interest

None of the authors has a financial or personal relationship with other people or organizations that could inappropriately influence (bias) their work, with the following exceptions: Susan Eshleman has collaborated on research studies with investigators from Abbott; Abbott has provided reagents for collaborative research studies.

Ethical Approval

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed Consent

Informed consent was obtained from all individual participants included in the study.

participants were classified as previously diagnosed based on ARV drug testing. Among participants classified as previously diagnosed, disclosure of a prior HIV diagnosis varied among study sites ($p=0.006$) and was more common among those who reported having sex with men only ($p=0.002$). ARV drug testing in addition to self-report improves the accuracy for identifying individuals with a prior HIV diagnosis.

Keywords

HIV; self-report; MSM; transgender women; Africa; ART

INTRODUCTION

Many efforts to curb the HIV epidemic include interventions to increase the frequency of HIV testing [1]. Research studies often use self-report to identify HIV-infected individuals who are not aware of their HIV status. The accuracy of those data may be compromised, if some HIV-infected individuals do not disclose their HIV status to study staff [2–4]. Study participants may be concerned that their information might be shared with people other than study staff, or that they may experience stigma, discrimination, or other social harms if their HIV status is disclosed [5–7]. Other factors may influence whether study participants report a prior HIV diagnosis (e.g., if a study limits the number of HIV-infected participants or excludes those who are previously diagnosed or in care, or if study interventions, support services, or other incentives are offered only to those with a new HIV diagnosis). Methodological factors may also impact the accuracy of self-reported data. For example, some participants may not understand interview questions, or there may be errors in collection or reporting of interview responses.

This study evaluated the accuracy of self-report of HIV status among men who have sex with men (MSM) and transgender women who have sex with men in a research study in Africa. MSM and transgender women in Africa are at high risk of HIV infection [8–11]. Criminalization of homosexuality in many countries, stigma, and fear of social harms have limited uptake of HIV prevention and treatment services among African MSM [7, 12, 13]. These factors may also discourage participants from disclosing their HIV status to research staff.

One approach for assessing the accuracy of self-report of HIV status was to identify participants who were on antiretroviral treatment (ART) by testing samples for the presence of antiretroviral (ARV) drugs. In a previous study, we used this approach to assess the accuracy of self-reported HIV status in a cohort of Black MSM in the United States (HIV Prevention Trials Network [HPTN] 061 study) [2]. In that study, 155 HIV-infected men reported no prior HIV diagnosis, including 83 men who had HIV viral loads $<1,000$ copies/mL. Retrospective ARV drug testing revealed that 65 (78.3%) of the 83 men were on ART, indicating that they were previously diagnosed with HIV infection and were aware of their HIV status. Based on those findings, the enrollment status of $>40\%$ of the HIV-infected men in the cohort was changed from newly diagnosed to previously diagnosed [2]. In this report, we used retrospective ARV drug testing to evaluate the accuracy of self-reported data

in the HPTN 075 study. The aim of HPTN 075 was to evaluate the feasibility of recruiting and retaining HIV-infected and HIV-uninfected MSM in sub-Saharan Africa for HIV prevention trials.

METHODS

Study cohort

Participants were screened for participation in HPTN 075 at four study sites (Kisumu, Kenya; Blantyre, Malawi; Soweto and Cape Town, South Africa; 2015–2016). The participants included in this substudy met the following criteria: age 18 to 44 years, assigned male sex at birth, reported ever having had sex with a man, agreed to have HIV testing, and had two positive/reactive HIV test results at the screening visit. Transgender women were eligible for participation in HPTN 075, but were not specifically recruited for the study. Questions asked about previous HIV testing, HIV status, and ART at the screening visit are shown in the Supplemental File 1. HIV-infected participants who were in care or on ART were not eligible to enroll in HPTN 075, and the number of HIV-infected participants enrolled was capped at 20 per study site.

Laboratory testing

HIV testing was performed at study sites at screening with two HIV rapid tests. Additional HIV testing, ARV drug testing, and viral load testing were performed retrospectively at the HPTN Laboratory Center (Baltimore, MD, US). ARV drug testing was performed using a qualitative, multi-drug assay based on high-performance liquid chromatography (HPLC) coupled with high-resolution accurate mass (HRAM) mass spectrometry [14, 15]. This assay can detect 20 ARV drugs in five drug classes (six nucleoside/nucleotide reverse transcriptase inhibitors [NRTIs], three non-nucleoside reverse transcriptase inhibitors [NNRTIs], nine protease inhibitors [PIs], one integrase strand transfer inhibitor, and one CCR5 receptor antagonist); the limit of detection for this assay is 2 or 20 ng/mL, depending on the drug [14]. HIV viral load testing was performed with the RealTime HIV-1 Viral Load Assay (Abbott Molecular, Abbott Park, IL). A validated dilution method was used for viral load testing because the volume of some plasma samples was limited; this method has a lower limit of quantification of 400 copies/mL HIV RNA.

Statistical analysis

Participants were classified as previously diagnosed if they reported that they were HIV-infected at screening or if ARV drugs were detected in their screening sample. Logistic regression was used to compare characteristics in two groups of participants who were confirmed to be HIV infected in the study: those who reported a prior diagnosis, and those who did not report a prior diagnosis, but had ARV drugs detected in their screening sample. $P < 0.05$ was considered significant.

Ethical considerations

Informed consent was obtained from all individuals who participated in screening for HPTN 075 (oral consent in Blantyre, Malawi; written consent at the other three study sites).

RESULTS

Study cohort

A total of 624 participants were screened for participation in HPTN 075. We analyzed samples and data from 183 of the 188 participants who tested positive for HIV infection at screening (five were excluded from analysis: two had inconclusive HIV test results, two reported sex with women only, and one was >44 years of age). The 183 HIV-infected participants included 166 who reported having had a previous HIV test. This included 67 who reported that their last HIV test was positive, 93 who reported that their last HIV test was negative, and six who did not report HIV status. Seventeen reported that they never had a prior HIV test (Figure 1).

Identification of previously-diagnosed participants

The 67 participants who reported a prior positive HIV test at screening were classified as previously diagnosed (Figure 1). ARV drug testing was performed for the remaining 116 HIV-infected participants who did not report that they had a prior positive HIV test; these participants were not asked about prior or current ARV drug use. At least one ARV drug was detected in samples from 36 (31.0%) of the 116 participants tested (13/18 [72.2%] from Kisumu, Kenya; 4/18 [22.2%] from Blantyre, Malawi; 8/34 [23.5%] from Cape Town, South Africa; 11/46 [23.9%] from Soweto, South Africa); these participants were classified as previously diagnosed based on the results of ARV drug testing (Figure 1). This included 30 participants who reported a negative HIV status at screening; five who reported having a prior HIV test, but did not answer the question about HIV status; and one who reported having a prior HIV test, but did not remember the result of the test. Thirty-one (86.1%) of the 36 participants had two or more drugs detected, consistent with ART. Five had a single drug detected (efavirenz); those five participants may have been taking NRTIs that were not detected because of their short half-lives. Overall, 29 (80.6%) of the 36 participants with ARV drugs detected were virally suppressed (<400 copies/mL); the remaining seven included three with viral loads between 400 and <1,000 copies/mL, and four with viral loads >1,000 copies/mL. After accounting for ARV drug use, 103 (56.3%) of the participants were classified as previously diagnosed and 80 (43.7%) were classified as newly diagnosed (Figure 1).

Factors associated with reporting a prior HIV diagnosis

We analyzed demographic and behavioral factors among the 103 participants who were classified as previously diagnosed at screening; two groups were compared: those who reported a prior HIV diagnosis, and those who did not report a prior HIV diagnosis, but had ARV drugs detected in the sample from their screening visit (Table 1). Report of a positive HIV status at screening was significantly associated with study site; those from Soweto, South Africa were more likely to report a positive HIV status than those from Kisumu, Kenya (77.6% vs. 43.5%; odds ratio [OR] 95% confidence interval [CI]: 4.49 [1.55–13.00]; $p=0.006$). Participants who reported that they had sex with men and women were less likely to report a positive HIV status than those who reported having sex with men only (50.0% vs. 79.2%, OR [95% CI]: 0.26 [0.11–0.62], $p=0.002$). Other demographic factors such as age

and gender identification (male compared to transgender) were not statistically associated with disclosure of a positive HIV status (Table 1).

DISCUSSION

In this report, approximately one third of the HIV-infected MSM or transgender women who did not report a prior HIV diagnosis to study staff had ARV drugs detected and were classified as previously diagnosed. Participants who were in care or on ART were not eligible to enroll in HPTN 075 and the number of HIV-infected participants enrolled was capped at each study site. Study staff were instructed not to disclose the eligibility criteria during the screening visit, so these factors were not likely to have influenced whether or not participants reported knowledge of their HIV status at that visit. However, some participants may have believed they would not be eligible for the study if they reported that they were HIV infected, and may therefore have chosen not to disclose their HIV status. Other factors may also have impacted the accuracy of the self-reported data, such as poor HIV literacy or misunderstanding of the interview questions.

Regional differences in self-reporting of HIV status were observed among participants who were classified as previously diagnosed. Self-report of a positive HIV status was less common at the study site in Kisumu, Kenya than at the study site in Soweto, South Africa, with intermediate levels of reporting at the other two study sites. Fear of arrest, stigma, or social harms with disclosure of HIV-positive status may have been higher among MSM in Kenya than South Africa. Homosexuality was decriminalized in South Africa over 20 years ago, but is still unlawful in Kenya [16, 17]. A survey among MSM in Kisumu, Kenya reported that 60% were uncomfortable seeking care in a public hospital [18]. That survey reported a high willingness of MSM to be contacted for participation in future HIV research studies. However, in-depth interviews revealed that the main reason for not wanting to participate was fear of personal information being shared outside of the study [18].

In HPTN 075, self-report of HIV positive status at screening was also less common among participants who reported sex with men and women compared to men who reported sex with men only. MSM who have sex with women may be more concerned about confidentiality of health information being shared outside of the study, especially if their partners did not know about their same-sex behaviors [10, 19]. Studies in Africa have reported a higher HIV prevalence among MSM who self-identified as gay compared to MSM who identified as bisexual or straight [10, 19, 20]. MSM who have sex with men only may be more open about their HIV status with their partners and friends and therefore may also be more likely to disclose their HIV status to staff in a research setting. A recent survey from the United Kingdom reported that HIV-infected MSM were more likely to report their HIV status to their stable partner, friends, family, and colleagues than HIV-infected heterosexual men [21]. Further information is needed to determine the reasons why MSM in some African settings may choose not to disclose their HIV status.

A limitation of this study is that ARV drug testing can only identify previously-diagnosed individuals if they are on ART. Participants who had no ARV drugs detected may also have been diagnosed with HIV infection prior to study screening. We detected ARV drugs in 72%

of the HIV-infected participants from Kisumu, Kenya who did not report an HIV-positive status, compared to only 22–24% at the other study sites. It is not clear whether participants at the Kenya site were less likely to report that they were infected, or if other factors impacted the regional difference in the proportion of participants on ART who did not report prior HIV diagnosis (e.g., if participants at this site had more access to HIV testing and ART, or if those on treatment were more interested in participating in a research study). Another limitation of this study is that it was not possible to determine the reason for ARV drug use in cases where only one drug was detected. In this study, five participants had efavirenz only detected. These participants may have been on an efavirenz-based ART regimen (with the NRTIs not detected due to poor adherence and/or shorter NRTI drug half-life) or could have been using efavirenz as a recreational drug [22, 23]. It is also possible that efavirenz could have been used for pre-exposure prophylaxis or post-exposure prophylaxis in individuals who were not aware that they were HIV-infected [24]. Finally, the analysis of factors associated with HIV disclosure among those previously diagnosed included relatively small numbers in each group (67 disclosed their HIV status and 36 did not).

The findings of this study demonstrate that self-report may not be accurate for identifying newly-diagnosed vs. previously-diagnosed HIV infections. Combining ARV drug testing with self-report provides a more accurate estimate of previously-diagnosed infections. This approach may still underestimate the portion of individuals with previously-diagnosed infection, since it will not identify previously-diagnosed individuals who are not on ART. Understanding factors associated with disclosure of HIV status in different populations and settings may help inform epidemiologic surveys of the HIV/AIDS epidemic and research studies for HIV treatment and prevention. The accuracy of self-reported data on HIV status might be improved by optimizing interview methods (e.g., by including cognitive testing of interview questions or adding confirmatory questions). Future research studies could also include in-depth interviews to gain more insight into discrepancies between self-reported knowledge of HIV status and results from objective measures, such as ARV drug testing.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Figure 1.

Classification of participants as newly diagnosed vs. previously diagnosed.

The chart shows the number of participants who were HIV-infected at the screening visit, self-reported data on HIV status, and results of antiretroviral (ARV) drug testing.

Participants were identified as previously diagnosed based on self-report and results from ARV drug testing.

^a The 116 participants included 93 who reported a HIV-negative status; the remaining 23 included 17 who reported no prior HIV test; five who reported having a previous HIV test, but did not know the result; and one who did not provide an answer.

Table 1.

Factors associated with disclosure of HIV status among men and transgender women classified as previously diagnosed who were screened for participation in HPTN 075.*

Variables	Previously-diagnosed study participants (N=103)			
	Total	HIV status disclosed (N, %)	OR (95% CI)	p-value
Age				
18–25 years	48	34 (70.8%)	ref	
26–44 years	55	33 (60.0%)	0.62 (0.27–1.41)	0.25
Study site				
Kisumu, Kenya	23	10 (43.5%)	ref	
Blantyre, Malawi	13	9 (69.2%)	2.92 (0.69–12.32)	0.14
Cape Town, South Africa	18	10 (55.6%)	1.62 (0.47–5.63)	0.44
Soweto, South Africa	49	38 (77.6%)	4.49 (1.55–13.00)	0.006
Gender identification^a				
Male	66	41 (62.1%)	ref	
Transgender	37	26 (70.3%)	1.44 (0.61–3.42)	0.41
Ever had sex with women				
No	53	42 (79.2%)	ref	
Yes	50	25 (50.0%)	0.26 (0.11–0.62)	0.002

* The table shows factors associated with disclosure of HIV status among 103 participants who were confirmed to be HIV infected in the study and who were classified as previously diagnosed. Two groups were compared; those who reported a prior HIV diagnosis at screening, and those who did not report a prior HIV diagnosis, but had ARV drugs detected in the sample from their screening visit. Sixty-seven participants reported that their last HIV test was positive (HIV status disclosed, Yes). Thirty-six participants did not report a previous positive HIV test, but were classified as previously diagnosed based on results of antiretroviral (ARV) drug testing (HIV status disclosed: No, see text). Data for variables shown in the table were collected at the screening visit. $p < 0.05$ is bolded. Abbreviations: N: number; OR: odds ratio; CI: confidence interval, ref: reference.

^aParticipants who identified as female, male and female, and/or transgender were classified as transgender.